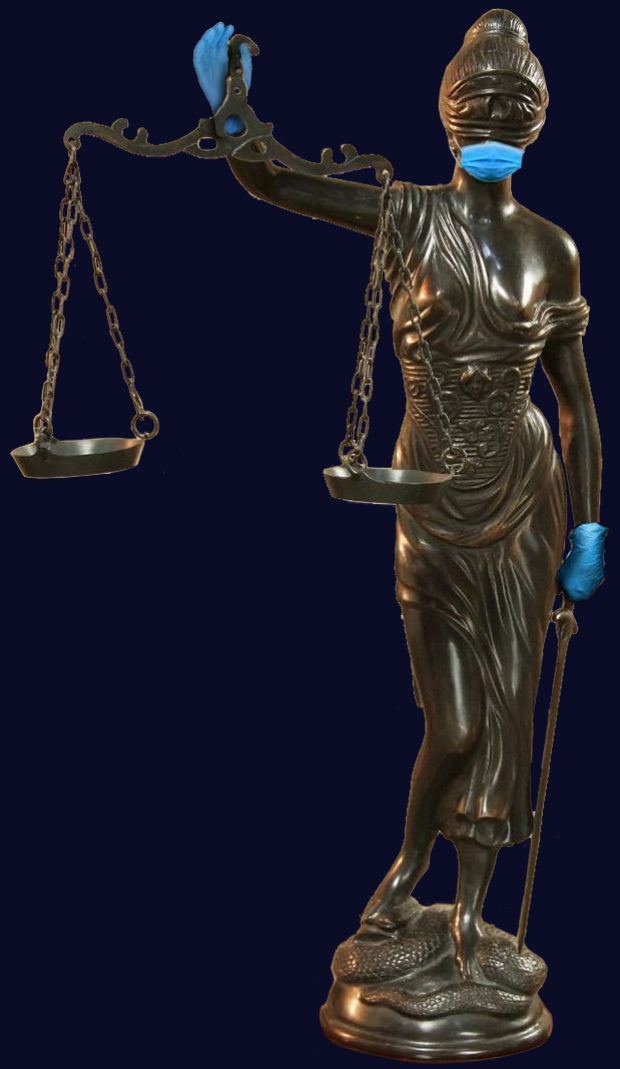

ICS 3

MAY 3, 2023 - BRUSSELS

(IL-)LEGALITIES SURROUNDING THE PANDEMIC

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Misuse of PCR-testing and the omission of medical care – the starting points for the illegal Covid-19 measures

What made non-scientific based Covid-19 measures, like

- lockdowns
- mask mandates
- market authorization of experimental so-called Covid-19-“vaccines” even with vaccine mandates in certain EU member states

possible?

1. misuse of PCR-testing outside the scientific gold standard (absurd high number of threshold cycles, non-consideration of clinical symptoms etc.) created enormous numbers of “cases”
2. omission of (and the right) medical treatment of patients.

Urgent need for a revocation of the market authorization of mRNA-Covid-19-“vaccines”

because of

- evident lack of a “vaccine”-efficacy
- enormous risks for health and life
- now even a 5 year renewable “standard” authorization

Gross Violation

Gross violation of

- TFUE, Articles 168 and 169
- EU Charter, Articles 3, 35 and 38
- Directive 2001/83/EC (Community Code relating to medicinal products) articles 8, 11, 26, 54, 58, 59, 86 et seq., 101 et seq., Annex I, Part I, Part III, Part IV
- Regulation (EC) No 726/2004 (Community procedures for authorization and supervision of medicinal products) Articles 3 to 7, 10a, 12, 14-a,
- UN Declaration on the Human Genome and Human Rights

by circumventing high testing standards provided for gene-based medicinal products

Directive 2009/120/EU

Illogical, scientifically not valid exclusion of substances formally declared as vaccines against infectious diseases from the category of the gene therapy products, despite of their composition and action

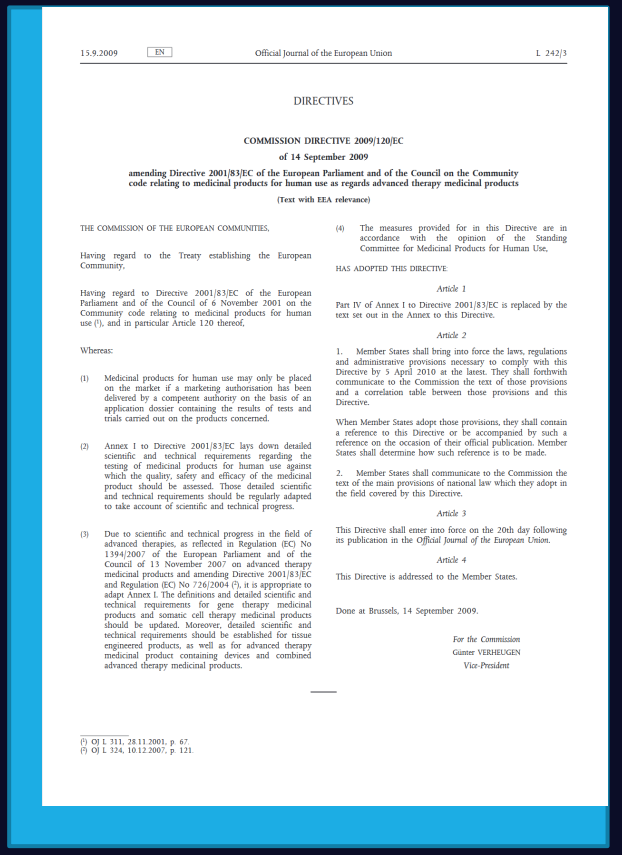
<u>Directive 2009/120/EU:</u>

"*Gene therapy medicinal products shall not include vaccines against infectious diseases*"

mRNA-"vaccines" are treated by EMA / European Commission as conventional vaccines

mRNA-"vaccines" have nothing in common with conventional vaccines

saves manufacturers numerous time-consuming and financially expensive preclinical studies



15.9.2009 EN Official Journal of the European Union L 242/3

DIRECTIVES

COMMISSION DIRECTIVE 2009/120/EC

of 14 September 2009

amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [1], and in particular Article 120 thereof,

Whereas:

(1) Medicinal products for human use may only be placed on the market if a marketing authorisation has been delivered by a competent authority on the basis of an application dossier containing the results of tests and trials carried out on the products concerned.

(2) Annex I to Directive 2001/83/EC lays down detailed scientific and technical requirements regarding the testing of medicinal products for human use against which the quality, safety and efficacy of the medicinal product should be assessed. Those detailed scientific and technical requirements should be regularly adapted to take account of scientific and technical progress.

(3) Due to scientific and technical progress in the field of advanced therapies, as reflected in Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 [2], it is appropriate to adapt Annex I. The definitions and detailed scientific and technical requirements for gene therapy medicinal products and somatic cell therapy medicinal products should be updated. Moreover, detailed scientific and technical requirements should be established for tissue engineered products, as well as for advanced therapy medicinal product containing devices and combined advanced therapy medicinal products.

(4) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Medicinal Products for Human Use,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Part IV of Annex I to Directive 2001/83/EC is replaced by the text set out in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 5 April 2010 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 September 2009.

For the Commission
Günter VERHEUGEN
Vice-President

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 324, 10.12.2007, p. 121.

Incalculable dramatic consequences for the Public Health

- No genotoxicity studies
- No carcinogenicity studies
- No mutagenicity (modification of DNA) studies

Reverse transcription of RNA into DNA is a mechanism that has been known for many decades (since the 1970s)!

Nothing new, nothing that can simply be ruled out.

Lipid nanoparticles can enter all kinds of cells – purpose of their inclusion

Certain lipids used have never been approved for use in humans.

Committee for Advanced Therapies was illegally not involved

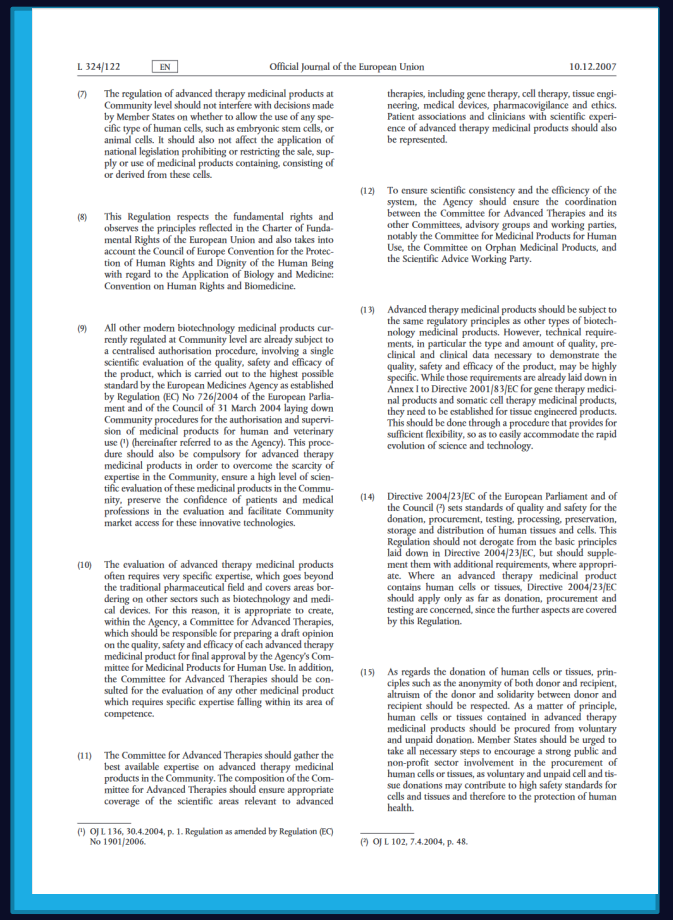
Committee for Advanced Therapies MUST be involved in authorization procedure, even if medicinal products would not be classified as advanced therapy medicinal products, but function in essential aspects like these

- recitals (8), (10), (11) (12) (13) (20) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products

Committee for Advanced Therapies

WAS NOT INVOLVED

in the market authorization of mRNA-“vaccines”



L 324/122 EN Official Journal of the European Union 10.12.2007

(7) The regulation of advanced therapy medicinal products at Community level should not interfere with decisions made by Member States on whether to allow the use of any specific type of human cells, such as embryonic stem cells, or animal cells. It should also not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products containing, consisting of or derived from these cells.

(8) This Regulation respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union and also takes into account the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.

(9) All other modern biotechnology medicinal products currently regulated at Community level are already subject to a centralised authorisation procedure, involving a single scientific evaluation of the quality, safety and efficacy of the product, which is carried out to the highest possible standard by the European Medicines Agency as established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use (1) (hereinafter referred to as the Agency). This procedure should also be compulsory for advanced therapy medicinal products in order to overcome the scarcity of expertise in the Community, ensure a high level of scientific evaluation of these medicinal products in the Community, preserve the confidence of patients and medical professions in the evaluation and facilitate Community market access for these innovative technologies.

(10) The evaluation of advanced therapy medicinal products often requires very specific expertise, which goes beyond the traditional pharmaceutical field and covers areas bordering on other sectors such as biotechnology and medical devices. For this reason, it is appropriate to create, within the Agency, a Committee for Advanced Therapies, which should be responsible for preparing a draft opinion on the quality, safety and efficacy of each advanced therapy medicinal product for final approval by the Agency's Committee for Medicinal Products for Human Use. In addition, the Committee for Advanced Therapies should be consulted for the evaluation of any other medicinal product which requires specific expertise falling within its area of competence.

(11) The Committee for Advanced Therapies should gather the best available expertise on advanced therapy medicinal products in the Community. The composition of the Committee for Advanced Therapies should ensure appropriate coverage of the scientific areas relevant to advanced therapies, including gene therapy, cell therapy, tissue engineering, medical devices, pharmacovigilance and ethics. Patient associations and clinicians with scientific experience of advanced therapy medicinal products should also be represented.

(12) To ensure scientific consistency and the efficiency of the system, the Agency should ensure the coordination between the Committee for Advanced Therapies and its other Committees, advisory groups and working parties, notably the Committee for Medicinal Products for Human Use, the Committee on Orphan Medicinal Products, and the Scientific Advice Working Party.

(13) Advanced therapy medicinal products should be subject to the same regulatory principles as other types of biotechnology medicinal products. However, technical requirements, in particular the type and amount of quality, preclinical and clinical data necessary to demonstrate the quality, safety and efficacy of the product, may be highly specific. While those requirements are already laid down in Annex I to Directive 2001/83/EC for gene therapy medicinal products and somatic cell therapy medicinal products, they need to be established for tissue engineered products. This should be done through a procedure that provides for sufficient flexibility, so as to easily accommodate the rapid evolution of science and technology.

(14) Directive 2004/23/EC of the European Parliament and of the Council (2) sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. This Regulation should not derogate from the basic principles laid down in Directive 2004/23/EC, but should supplement them with additional requirements, where appropriate. Where an advanced therapy medicinal product contains human cells or tissues, Directive 2004/23/EC should apply only as far as donation, procurement and testing are concerned, since the further aspects are covered by this Regulation.

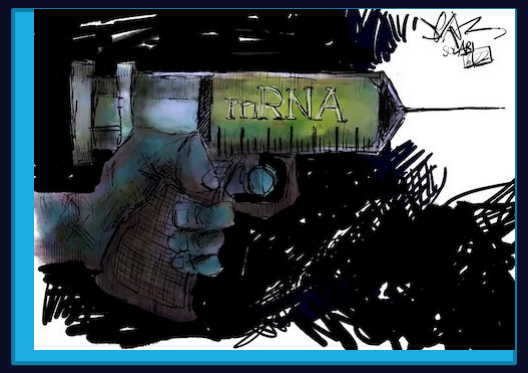
(15) As regards the donation of human cells or tissues, principles such as the anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient should be respected. As a matter of principle, human cells or tissues contained in advanced therapy medicinal products should be procured from voluntary and unpaid donation. Member States should be urged to take all necessary steps to encourage a strong public and non-profit sector involvement in the procurement of human cells or tissues, as voluntary and unpaid cell and tissue donations may contribute to high safety standards for cells and tissues and therefore to the protection of human health.

(1) OJ L 136, 30.4.2004, p. 1. Regulation as amended by Regulation (EC) No 1901/2006.

(2) OJ L 102, 7.4.2004, p. 48.

Non-observance of authorization requirements for vaccines based on genetic engineering

- EMA/European Commission did even non observe the specific guidelines for DNA vaccines
- They explicitly and exclusively refer to the WHO guidelines for conventional vaccines
- WHO guidelines are in principle not binding in any way.
- The mere reference to the WHO guidelines for conventional vaccines is absolutely unacceptable!
- EMA states: no genotoxicity and carcinogenicity studies were carried out because the components of the substance (lipids and RNA) are “not expected” to have any genotoxic potential!



- EMA confirms that “Russian roulette is being played” with the entire unsuspecting EU population (and their descendants).

Gross Violation

Gross violation of

TFUE Articles 168 and 169 TFEU

EU CHARTER OF FUNDAMENTAL RIGHTS Articles 3, 35 and 38

Directive 2001/83/EC Articles 8, 11, 26, 54, 58, 59, 86 and ff, 101 and ff, Annex I, Part I, Part III, Part IV,

Regulation (EC) No 726/2004 Articles 3 to 7, 10a, 12, 14, 14a, 20, 20a, 25a, 57, 81, 84a,

Commission Regulation (EC) No 507/2006 Articles 5 and 7

Notwithstanding the

- omission of the most fundamental studies the initially only conditional marketing authorization

of the mRNA-"vaccines" COMIRNATY (Pfizer/BioNTech) and Spikevax (Moderna)

- market authorization was converted into an 5 years valid authorization without specific conditions!

Non-fulfilment of specific obligations imposed for the conditional marketing authorization of the Covid-19-"Vaccines"

- Violation of Article 14-a of Regulation (EC) No 726/2004 and Commission Regulation (EC) No 507/2006
- Non-completion of ongoing clinical studies or the non-beginning of new studies to confirm the positive risk-benefit balance within 2023 and 2024.
- Placebo group was cancelled already in early 2021
- Efficacy and safety have never been clinically tested and confirmed!

Conditional marketing authorization of medicinal products

according to Regulation (EC) No 726 2004 Article 14-a point (3) possible only if

- risk-benefit balance is positive
- applicant is likely to be able to provide comprehensive data

Only after the fulfillment of the specific obligations set out in paragraph 4 of Article 14-a of Regulation (EC) No 726/2004 a renewable market authorization valid for 5 years is possible.

If a holder of an authorization granted in accordance with Article 14-a of Regulation (EC) No 726/2004 has failed to comply with the obligations laid down in the authorization,

- immediate suspension or revoke of the authorization is obligatory.

BioNTech and Moderna have disbanded in early 2021 the control groups of their clinical studies

Instead of immediately revoking the conditional authorization, the European Commission

- granted the regular marketing authorization
- declared that the specific conditions of the conditional marketing authorization were fulfilled!

Which is clearly the untruth!

A Mass Experiment

EU population handed over by EU Commission and EMA to a mass experiment as guinea pigs for experimental substances based on genetic engineering

Gross violation of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use.

- Medicinal treatment may only be carried out with the free informed consent of the person concerned

EU population was and is kept in the dark about

- real nature of the substances injected,
- disastrous risk-benefit balance,
- missing of essential study data,
- lack of adequate pharmacovigilance.

Only those who are correctly and fully informed can make a “free” decision:

- population deliberately misled has not been able to make a “free” decision
- all “consent forms” signed by vaccinees are null and void.

Conditions for the applicability of Commission Regulation (EC) No 507/2006

Conditions for the applicability of Commission Regulation (EC) No 507/2006 have been artificially created in order to place the experimental Covid-19-“vaccinese” on the market.

Conditional authorization of medicinal product possible only, if the medicinal product is:

- intended for the treatment or prevention of seriously debilitating or life-threatening diseases
- intended to be used in emergency situations against a threat to public health identified either by the WHO or by the EU.

PHEIC could be declared only after beginning of brazen misuse of the RT-qPCR test and worldwide creation of enormous numbers of false positive SARS-CoV-2 infection cases

Never a real PHEIC also because of the overall low Infection Fatality Rate (IFR)

At no time existed conditions for a conditional marketing authorization of the experimental covid-19-injections

Further conditions for the conditional marketing authorization (Article 4 Commission Regulation EC 507/2006)

a) positive risk-benefit balance;

b) applicant expected to be able to provide the comprehensive clinical data;

c) medical care gap can be closed;

d) public health benefit of the immediate availability of the medicinal product on the market outweighs the risk due to the lack of additional data.

a) A positive risk-benefit ratio could never be established, due to

- generally low *infection fatality rate* (comparable to that of a moderate flu for the total population and de facto zero for children and adolescents)
- serious side effect cases recorded in the EudraVigilance database (including thousands of fatalities and hundreds of thousands of other most serious irreversible side effects)

b) Applicants disbanded in early 2021 the placebo group – no clinical trial data for confirmation of efficacy or safety

c) proven by thousands of doctors worldwide: there has never been a de facto gap in medical care.

d) there is no evidence of any benefit to public health, on the contrary.

Gross violation of TFUE articles 168 and 169 and EU Charter Articles 3, 35 and 38

- The EU legislator guaranteed a high level of health protection and high standards of quality and safety for medicinal products and medical devices

Article 3 EU Charter (right to integrity):

(1) Everyone has the right to respect for his or her physical and mental integrity

(2) In the fields of medicine and biology, …must be respected in particular: the free informed consent of the person concerned, …, the prohibition on making the human body and its parts as such a source of financial gain, ….

Article 35 EU Charter (health protection), every person … is guaranteed a high level of health protection in the definition and implementation of all Union policies and activities.

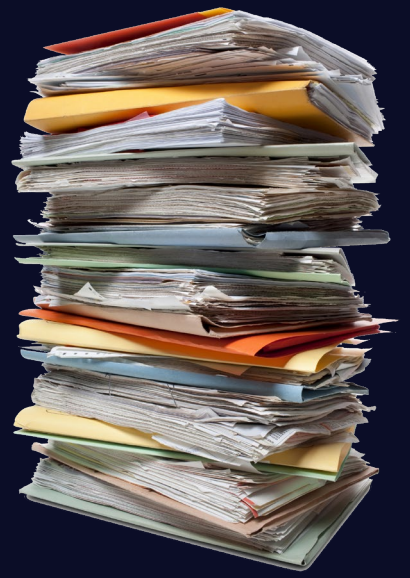
Article 169 TFEU (consumer protection) consumers are guaranteed that … the EU shall contribute to protecting the health and safety of consumers and to promoting their right to information.

Article 38 EU Charter (Consumer Protection): policies of the Union shall constitute a high level of consumer protection.

Actions for annulment according to Art. 263 TFUE pending before the European Court

against authorization of

- Comirnaty of Pfizer/BioNTech (T-109/23)
- Spikevax of Moderna (T-108/23)



Legal procedure documents (action for annulment, etc.) are published on Children's Health Defense Europe website: www.childrenshealthdefense.eu

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